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What is claimed is:

1. A pharmaceutical composition comprising
micronized eplerenone in an amount of about 10 mg to
about 1000 mg and a pharmaceutically acceptable
5 carrier material.

2. The pharmaceutical composition
according to claim 1 wherein said composition
comprises micronized eplerenone in an amount of about
10 20 mg to about 400 mg.

3. The pharmaceutical composition
according to claim 1 wherein said composition
comprises micronized eplerenone in an amount of about
15 25 mg to about 150 mg.

4. The pharmaceutical composition
according to claim 1 wherein said composition
comprises micronized eplerenone in an amount of about
20 25 mg to about 100 mg.

5. The pharmaceutical composition
according to claim 1 wherein said carrier material is
cellulosic, and said cellulosic carrier material is
25 selected from the group consisting of purified
cellulose, microcrystalline cellulose, and alkyl
celluloses and their derivatives and salts.

6. The pharmaceutical composition
30 according to claim 1 comprising one or more
pharmaceutically acceptable binding agents, wherein

said binding agent or binding agents are present at about 0.5% to about 25% of the total weight of the composition.

5 7. The pharmaceutical composition
according to claim 6 wherein said binding agents are
selected from the group consisting of acacia,
tragacanth, sucrose, gelatin, glucose, starch,
celluloses, alginic acid, salts of alginic acid,
10 magnesium aluminum silicate, polyethylene glycol,
gums, polysaccharide acids, bentonites,
polyvinylpyrrolidone, polymethacrylates,
hydroxypropyl methylcellulose, hydroxypropyl
cellulose, ethyl cellulose, and pregelatinized
15 starch.

8. The pharmaceutical composition
according to claim 1 comprising one or more
pharmaceutically acceptable diluents, wherein said
20 diluent or diluents are present at about 5% to about
99% of the total weight of the composition.

9. The pharmaceutical composition
according to claim 8 wherein said diluents are
25 selected from the group consisting of lactose,
starch, mannitol, sorbitol, dextrose,
microcrystalline cellulose, dibasic calcium
phosphate, sucrose-based diluents, confectioner's
sugar, monobasic calcium sulfate monohydrate, calcium
30 sulfate dihydrate, calcium lactate trihydrate,
dextrates, inositol, hydrolyzed cereal solids,

amylose, powdered cellulose, calcium carbonate, glycine, and bentonite.

10. The pharmaceutical composition
5 according to claim 1 comprising one or more pharmaceutically acceptable disintegrants, wherein said disintegrants are present at about 0.5% to about 30% of the total weight of the composition.

10 11. The pharmaceutical composition according to claim 10 wherein said disintegrants are selected from the group consisting of starches, sodium starch glycolate, clays, celluloses, alginates, pregelatinized corn starches,
15 crospovidone, and gums.

12. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable wetting agents, wherein
20 said wetting agents or wetting agents are present at about 0.1% to about 15% of the total weight of the composition.

13. The pharmaceutical composition
25 according to claim 12 wherein said wetting agents are selected from the group consisting of oleic acid, glyceryl monostearate, sorbitan mono-oleate, sorbitan monolaurate, triethanolamine oleate, polyoxyethylene sorbitan mono-oleate, polyoxyethylene sorbitan
30 monolaurate, sodium oleate, and sodium lauryl sulfate.

14. The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable lubricants, wherein said
5 lubricant or lubricants are present at about 0.1% to about 10% of the total weight of the composition.

15. The pharmaceutical composition according to claim 14 wherein said lubricants are
10 selected from the group consisting of glyceryl behenate, stearates, stearic acid, hydrogenated vegetable oils, talc, waxes, Stearowet, boric acid, sodium benzoate, sodium acetate, sodium chloride, DL-Leucine, polyethylene glycols, sodium oleate, sodium
15 lauryl sulfate, and magnesium lauryl sulfate. stearate.

16. The pharmaceutical composition according to claim 1 comprising one or more
20 pharmaceutically acceptable anti-adherents or glidants, wherein said anti-adherent or anti-adherents or glidants are present at about 0.25% to about 10% of the total weight of the composition.

25 17. The pharmaceutical composition according to claim 16 wherein said anti-adherents or glidants are selected from the group consisting of talc, cornstarch, DL-Leucine, sodium lauryl sulfate, and metallic stearates.

18. The pharmaceutical composition according to claim 6 wherein said micronized eplerenone is present at about 1% to about 90% of the total weight of the composition.

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19. The pharmaceutical composition according to claim 18 comprising one or more carrier materials selected from the group consisting of diluents, binding agents, disintegrants, wetting agents, lubricants and anti-adherents or glidants.

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20. The pharmaceutical composition according to claim 18 comprising hydroxypropyl methylcellulose.

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21. The pharmaceutical composition according to claim 18 comprising lactose.

22. The pharmaceutical composition according to claim 18 comprising microcrystalline cellulose.

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23. The pharmaceutical composition according to claim 18 comprising croscarmellose sodium.

25

24. The pharmaceutical composition according to claim 1 comprising:

lactose at about 5% to about 90% of the total weight of the composition;

30

microcrystalline cellulose at about 5% to about 90% of the total weight of the composition; and hydroxypropyl methylcellulose at about 0.5% to about 10% of the total weight of the composition.

5

25. The pharmaceutical composition according to claim 1 comprising:

about 1 to about 90 weight percent of micronized eplerenone;

10 about 5 to about 90 weight percent of lactose;

about 5 to about 90 weight percent of microcrystalline cellulose; and

15 about 0.5 to about 10 weight percent of hydroxypropyl methylcellulose.

26. The pharmaceutical composition according to claim 1 comprising:

20 about 19 to about 40 weight percent of micronized eplerenone;

about 32 to about 52 weight percent of lactose;

about 8 to about 28 weight percent of microcrystalline cellulose; and

25 about 1 to about 8 weight percent of hydroxypropyl methylcellulose.

27. The pharmaceutical composition according to claim 1 comprising:

30 about 24 to about 35 weight percent of micronized eplerenone;

about 37 to about 47 weight percent of
lactose;

about 13 to about 23 weight percent of
microcrystalline cellulose;

5 about 2 to about 6 weight percent of
croscarmellose sodium; and

about 2 to about 4 weight percent of
hydroxypropyl methylcellulose.

10 28. The pharmaceutical composition
according to claim 1 comprising:

about 28 to about 31 weight percent of
micronized eplerenone;

15 about 41 to about 43 weight percent of
lactose monohydrate;

about 17 to about 19 weight percent of
microcrystalline cellulose;

about 4.5 to about 5.5 weight percent of
croscarmellose sodium; and

20 about 2.5 to about 3.5 weight percent of
hydroxypropyl methylcellulose.

29. The pharmaceutical composition
according to claim 1 in the form of a coated or
25 uncoated unit dosage tablet wherein the uncoated
tablet or the coated tablet prior to coating
comprises:

about 29.4 weight percent of micronized
eplerenone;

30 about 42 weight percent of lactose;

about 18.1 weight percent of
microcrystalline cellulose;

about 5 weight percent of croscarmellose
sodium;

5 about 3 weight percent of hydroxypropyl
methylcellulose;

about 1 weight percent of sodium lauryl
sulfate;

10 about 1 weight percent of talc; and
about 0.5 weight percent of magnesium
stearate.

30. The pharmaceutical composition
according to claim 1 comprising:

15 about 23 mg to about 27 mg of micronized
eplerenone;

about 34 mg to about 38 mg of lactose;

about 14 mg to about 17 mg of
microcrystalline cellulose;

20 about 3 mg to about 6 mg of croscarmellose
sodium;

about 1 mg to about 4 mg of hydroxypropyl
methylcellulose;

25 about 0.25 mg to about 1.5 mg of sodium
lauryl sulfate;

about 0.25 mg to about 1.5 mg of talc; and
about 0.1 mg to about 1 mg of magnesium
stearate.

30 31. The pharmaceutical composition
according to claim 1 comprising:

about 48 mg to about 52 mg of micronized
eplerenone;

about 70 mg to about 73 mg of lactose;

about 29 mg to about 33 mg of

5 microcrystalline cellulose;

about 6 mg to about 10 mg of croscarmellose
sodium;

about 4 mg to about 6 mg of hydroxypropyl
methylcellulose;

10 about 1 to about 2.5 mg of sodium lauryl
sulfate;

about 1 to about 2.5 mg of talc; and

about 1 mg to about 1.5 mg of magnesium
stearate.

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32. The pharmaceutical composition
according to claim 1 comprising:

about 98 mg to about 102 mg of micronized
eplerenone;

20 about 141 mg to about 145 mg of lactose;

about 60 mg to about 64 mg of
microcrystalline cellulose;

about 16 mg to about 18 mg of
croscarmellose sodium;

25 about 9 mg to about 11 mg of hydroxypropyl
methylcellulose;

about 3 mg to about 4 mg of sodium lauryl
sulfate;

about 3 mg to about 4 mg of talc; and

30 about 1 mg to about 2 mg of magnesium
stearate.

33. The pharmaceutical composition according to claim 1 in a unit oral dosage form.

5 34. The pharmaceutical composition according to claim 1, wherein said composition is in the form of a unit dosage tablet or capsule.

 35. The pharmaceutical composition
10 according to claim 1, wherein said composition is in the form of a unit dosage tablet.

 36. The pharmaceutical composition according to claim 35 wherein the unit dosage tablet
15 is a coated unit dosage tablet.

 37. The pharmaceutical composition according to claim 1 in the form of an oral unit dosage tablet or capsule having a 25 mg, 50 mg or 100
20 mg dose of eplerenone.

 38. A pharmaceutical composition comprising micronized eplerenone and β -cyclodextrin in a liquid dosage form.
25

 39. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutical carrier material, wherein said composition is suitable for once or twice a day oral administration
30 as an aldosterone receptor blocker.

40. The pharmaceutical composition according to claim 1 wherein said composition provides a therapeutic effect as an aldosterone receptor blocker in a human subject over an interval of about 12 to about 24 hours after ingestion.

41. The pharmaceutical composition according to claim 1 wherein said composition provides a therapeutic effect as an aldosterone receptor blocker over an interval of about 24 hours after ingestion.

42. The pharmaceutical composition according to claim 1 wherein at least 50% of the eplerenone in the composition is released *in vitro* within 20 minutes in 0.1 N HCl.

43. The pharmaceutical composition according to claim 42 in the form of an oral dosage tablet or capsule suitable for once or twice a day oral administration.

44. The pharmaceutical composition according to claim 1 in the form of an oral dosage tablet or capsule suitable for once a day oral administration, and wherein at least 50% of the micronized eplerenone in the composition is released *in vitro* within 15 minutes in 0.1 N HCl.

45. The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the

composition is directly encapsulated or directly compressed into tablets.

46. The unit oral dosage form of the
5 pharmaceutical composition of claim 33 wherein the composition is wet granulated and encapsulated or compressed into tablets.

47. The unit oral dosage form of the
10 pharmaceutical composition of claim 33 wherein the composition is dry granulated and encapsulated or compressed into tablets.

48. The pharmaceutical composition
15 according to claim 1 wherein at least 90% of the micronized eplerenone particles used in the preparation of the pharmaceutical composition are less than about 200 microns in size.

20 49. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are less than about 150 microns in size.

25 50. The pharmaceutical composition according to claim 1 wherein at least 90% of the eplerenone particles used in the preparation of the pharmaceutical composition are about 30 to about 110
30 microns in size.

51. The pharmaceutical composition
according to claim 1 wherein at least 90% of the
eplerenone particles used in the preparation of the
pharmaceutical composition are about 30 to about 50
5 microns in size.

52. The pharmaceutical composition
according to claim 1 wherein at least 90% of the
eplerenone particles used in the preparation of the
10 pharmaceutical composition are about 50 to about 150
microns in size.

53. The pharmaceutical composition
according to claim 1 wherein at least 90% of the
15 eplerenone particles used in the preparation of the
pharmaceutical composition are about 75 to about 125
microns in size.

54. A pharmaceutical composition
20 comprising micronized eplerenone and a
pharmaceutically acceptable carrier material, wherein
said composition causes an average increase in blood
serum renin concentrations in a human subject over an
interval of about 12 to 24 hours after ingestion of
25 the composition of at least about 10%.

55. A pharmaceutical composition
comprising micronized eplerenone and a
pharmaceutically acceptable carrier material, wherein
30 said composition causes an average increase in blood
serum aldosterone concentrations in a human subject

over an interval of about 12 to 24 hours after
ingestion of the composition of at least about 50%.

56. A pharmaceutical composition
5 comprising micronized eplerenone and a
pharmaceutically acceptable carrier material, wherein
said composition causes an average decrease in
diastolic blood pressure in a human subject over an
interval of about 12 to 24 hours after ingestion of
10 the composition of at least about 5%.

57. The method of treating a condition or
disorder where treatment with an aldosterone receptor
blocker is indicated, comprising orally administering
15 a composition according to claim 1 to a patient in
need of such treatment.

58. The method according to claim 57
wherein the condition or disorder is heart failure.
20

59. The method according to claim 57
wherein the condition or disorder is hypertension.

60. The method according to 57 wherein the
25 condition or disorder is edema associated with liver
insufficiency.

61. The method according to claim 57
wherein the condition or disorder is post-myocardial
30 infarction.

62. The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering a composition according to claim 18 to a patient in
5 need of such treatment.

63. The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering
10 a composition according to claim 26 to a patient in need of such treatment.

64. A method of preparing a pharmaceutical composition comprising eplerenone comprising:
15 wet granulating micronized eplerenone and one or more carrier materials to form a wet granulated mixture; and
preparing an oral dosage form of the pharmaceutical composition from the wet granulated
20 mixture.

65. The method of claim 64 wherein the pharmaceutical composition is prepared in an oral unit dosage form comprising micronized eplerenone in
25 an amount of about 25 mg, 50 mg or 100 mg.

66. Use of micronized eplerenone and a cellulosic carrier material in the manufacture of a medicament for the treatment or prophylaxis of
30 aldosterone mediated conditions or disorders.

67. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition is an oral dosage form in which at least 50% of the eplerenone in the composition is released in vitro at least about 1.5 hours in 1% SDS.

68. The pharmaceutical composition according to claim 67 comprising:

10 about 24 to about 35 weight percent of micronized eplerenone;

 about 25 to about 45 weight percent of lactose;

 about 10 to about 25 weight percent of microcrystalline cellulose; and

15 about 5 to about 50 weight percent of hydroxypropyl methylcellulose.

69. A pharmaceutical composition comprising micronized eplerenone and a pharmaceutically acceptable carrier material, wherein said composition is an oral dosage form wherein at least 50% of the micronized eplerenone in the composition is released in vitro at least about 3.5 hours in 1% SDS.

70. The pharmaceutical composition according to claim 69 comprising:

 about 24 to about 35 weight percent of

30 micronized eplerenone;

about 25 to about 45 weight percent of
lactose;

about 10 to about 25 weight percent of
microcrystalline cellulose; and

5 about 5 to about 50 weight percent of
hydroxypropyl methylcellulose.

71. A pharmaceutical composition
comprising micronized eplerenone and a
10 pharmaceutically acceptable carrier material, wherein
said composition is an oral dosage form wherein at
least 50% of the micronized eplerenone in the
composition is released in vitro at least about 5.5
hours in 1% SDS.

15

72. The pharmaceutical composition
according to claim 71 comprising:

about 24 to about 35 weight percent of
micronized eplerenone;

20 about 25 to about 45 weight percent of
lactose;

about 10 to about 25 weight percent of
microcrystalline cellulose; and

25 about 5 to about 50 weight percent of
hydroxypropyl methylcellulose.